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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,124	10/03/2006	Abraham J. Domb	27617U	7340
20529 THE NATH I	7590 11/08/201 AW GROUP	EXAM	INER	
112 South We	st Street	HALL, DEANNA K		
Alexandria, V	A 22314		ART UNIT	PAPER NUMBER
		3767		
			MAIL DATE	DELIVERY MODE
			11/08/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.	Applicant(s)		
10/591,124	DOMB ET AL.		
Examiner	Art Unit		
DEANNA K. HALL	3767		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply

earned patent term adjustment	t. See 37 CFR 1.704(b).
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WHIC - Exte	ORTENED STATUTORY PERIOD CHEVER IS LONGER, FROM THE nsions of time may be available under the provision SIX (6) MONTHS from the mailing date of this con	MAILING DATE OF THIS ns of 37 CFR 1.136(a). In no event	DEXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, S COMMUNICATION. 1, however, may a reply be timely filed			
- If NC - Failu Any	period for reply is specified above, the maximum	statutory period will apply and will only will, by statute, cause the applications	expire SIX (6) MONTHS from the mailing date of this communication, ation to become ABANDONED (35 U.S.C. § 133). munication, even if timely filed, may reduce any			
Status						
1)🛛	Responsive to communication(s) filed on <u>9/1/11</u> .					
	This action is FINAL.					
3)	Since this application is in conditio	ce this application is in condition for allowance except for formal matters, prosecution as to the merits is				
	closed in accordance with the pract	tice under <i>Ex parte Qua</i>	yle, 1935 C.D. 11, 453 O.G. 213.			
Dispositi	ion of Claims					
4) 🖾	4) Claim(s) 1-36 is/are pending in the application.					
	4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.					
5)	Claim(s) is/are allowed.					
6)🛛	Claim(s) 18-36 is/are rejected.					
	Claim(s) is/are objected to.					
8)	Claim(s) are subject to restr	riction and/or election red	quirement.			
Applicati	ion Papers					
9)	The specification is objected to by t	he Examiner.				
10)	The drawing(s) filed on is/ar	e: a) accepted or b)	objected to by the Examiner.			
	Applicant may not request that any obj	ection to the drawing(s) be	held in abeyance. See 37 CFR 1.85(a).			
	Replacement drawing sheet(s) including	ng the correction is required	d if the drawing(s) is objected to. See 37 CFR 1.121(d).			
11)	The oath or declaration is objected	to by the Examiner. Note	e the attached Office Action or form PTO-152.			
Priority (ınder 35 U.S.C. § 119					
12)	Acknowledgment is made of a clair	n for foreign priority unde	er 35 U.S.C. § 119(a)-(d) or (f).			
a)	☐ All b)☐ Some * c)☐ None of:					
	 Certified copies of the priorit 	y documents have been	received.			
	2. Certified copies of the priority documents have been received in Application No					
	3. Copies of the certified copies of the priority documents have been received in this National Stage					
	application from the Internat	,				
- 8	See the attached detailed Office act	ion for a list of the certific	ed copies not received.			
Attachmen	rt(s)					
1) Notice of References Cited (PTO-892)			4) Interview Summary (PTO-413) Paper No(s)/Mail Date			
	e of Draftsperson's Patent Drawing Review mation Disclosure Statement(s) (PTO/SB/08	Paper No(s)/Mail Date 5) Notice of informal Patent Application				
	r No(s)/Mail Date		6) Other:			

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DETAILED ACTION

Acknowledaments

This office action is in response to the reply filed on 9/1/11.

 In the reply, the applicant amended claim 18 and added new claim 36. Claims 1-36 are pending with claims 1-17 being withdrawn.

Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made
- 4. Claims 18-22, 26-29, 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al. (US 4,250,878) ("Jacobsen") in view of Sun et al. (US 2002/0115957) ("Sun"). Jacobsen discloses a porous structure 82, 86 capable of absorbing and holding at least 30% w/w aqueous solutions without dissolving or disintegrating C5L21-22, the porous structure comprising a surface area of contact 82 with the tissue C5L16-20.
- Jacobsen discloses the invention as substantially claimed; however, Jacobsen does not directly disclose a data transmitting module capable to transmit data indicative

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of one or more of sponge size and surface area of contact of the sponge with tissue of a subject are intended use limitations. Sun, in the analogous art, teaches a data transmitting module [0087]. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Jacobsen with the data transmitting module to ensure safety of the delivery operation. The transmitting module of Sun is a chip 622, Fig. 6. It is inherent that the transmitting module is coated with a water protecting coat as to not disrupt the electronic conductivity with the electronic control unit 626 and conductive wire 624. The chip is a type of micro transmitter.

The porous structure of Jacobsen could also comprise a non-hydrophilic polymer such as polyurethane and a hydrophilic substance having at least one functional group such as a hydroxyl group [0050] as taught by Sun.

The object of Jacobsen is to by iontophoresis, delivery a chemical species into the skin or tissue of a person and to provide such a method and bioelectrode which may be used on irregular skin surfaces to facilitate substantially uniform contact with skin surfaces having a variety of shapes C1L65-C2L10. Thus, it the examiner's position that the device of Jacobsen could be used on eye tissue being sclera tissue or cornea tissue; the surface area of contact being a substantially planar surface.

Jacobsen discloses the delivery of a charged drug, see abstract, but does not further disclose specific chemical species to be delivered. The sponge (reservoir) of Sun comprises a charged drug [0050] such as an anesthetic [0003]; or an antibiotic such as gentamycin [0027] for delivery.

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 Claims 23-25, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen in view of Sun further in view of Nicolais et al. (US 5,645,592)
 ("Nicolais").

Jacobsen/Sun discloses the invention as substantially claimed (see above). However, the sponge of Jacobsen/Sun is not specifically disclosed as being comprised of a HEMA-methyl methacrylate copolymer. Sponges and hydrogels are known equivalents to those skilled in the art. Nicolais, in the analogous art, teaches the use of a hydrogel comprised of a HEMA-methyl methacrylate copolymer C7L20-44 in order to increase water absorption. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the sponge of Jacobsen/Sun by coating it with HEMA-methyl methacrylate copolymer as taught by Nicolais for the purpose of increasing water absorption.

Claim 30 is interpreted as a product by process claim (see MPEP 2113) which is read as a product claim. Thus, the sponge of Jacobsen/Sun/Nicolais is made of a hydroxyl methyl acrylate and ethylene glycol dimethacrylate copolymer.

Response to Arguments

7. Applicant's arguments have been fully considered but they are not persuasive.
Applicant argues that, whether taken alone or in combination, Jacobsen and Sun do not teach or suggest a sponge having tissue contacting surface area, a porous structure which is capable of absorbing and holding at least 30% w/w of an aqueous solution of

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charged drug. This argument is not persuasive. Examiner maintains that the porous structure of Jacobsen (80 as a whole could be interpreted as the porous structure) comprises a surface area 82 of contact with the tissue C5L20-22 (specifically discloses the pouch 82 as being microporous). The porous structure is both 86 and 82 and not just 86 as applicant's arguments suggest.

Further, applicant argues that there is no suggestion or motivation to modify the apparatus of Jacobsen to remove the exterior pouch/wall such that the sponge would directly contact tissue. Examiner is unclear of this argument because this modification was not suggested by examiner. It is unnecessary to remove the exterior pouch 82 in order for the porous structure to contact the tissue because in fact the exterior pouch 82 is in itself a porous structure that contacts the tissue C5L20-22.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEANNA K. HALL whose telephone number is (571)272-2819. The examiner can normally be reached on M-F 11:00am-7:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DEANNA K HALL/ Examiner, Art Unit 3767

/(Jackie) Tan-Uyen T. Ho/ Supervisory Patent Examiner, Art Unit 3763